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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,219	11/16/2006	David Helton	15513-1US	4859

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,219	HELTON ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 19-21* is/are pending in the application.

4a) Of the above claim(s) *10-16 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9* is/are rejected.

7)☒ Claim(s) *7-8, and 19-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/07, 10/13/08, 12/02/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-16 and 19-21 are currently pending in the application.

Applicant's election with traverse to various groups in the reply filed on 03/06/09 is acknowledged. The traversal is on the ground(s) that Flick recites a compound wherein R6 in formula III is a “CH” group while applicant's claims do not recite “hydrogen" at the R6 position. This is not found persuasive because the “hydrogen” of the prior art and the “methyl” (which falls under the heading of an alkyl as claimed by applicant) would have been obvious and thus expected to possess similar properties. Moreover, the Examiner contends that the compounds of the prior art and the instant invention are substantially similar in structure and thus are considered obvious variants. As a result, the Examiner asserts that the compounds were indeed known at the time of applicant's invention and thus no special technical features exist among the different groups (i.e. the composition vs. the method) and further fail to make a contribution over the prior art with respect to novelty and inventive. The Examiner further acknowledges the declaration of David Helton wherein compound of formula A was denoted to be more bioavailable than compound C, for example, when administered to rats. However, the comparison was between compound A which contains a “chlorine” at the R6 position and compound C which possesses a “hydrogen” at the same R6 position. Such comparison does not commensurate in scope with the invention since “hydrogen” still renders obvious a “methyl” group at that position. The Examiner thus asserts that

those compounds are expected to be structurally similar and behave similarly. As a result, there is a lack of unity of inventions and restriction for examination purposes as indicated was indeed proper.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 10-16 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 1-9 and 19-20 are examined on the merits herein. The Examiner further acknowledges that the elected species 1-{4-[4-(3,4-dichlorophenyl)piperazin-1-yl]butyl}-1,5,6,7-tetrahydroindol-4-one is free of the art, the search was extended to non-elected species.

Objections

Claims 1-9 and 19-20 are objected to because of the following informalities: Claims recite the limitation wherein R1 or R2 is an “aralky” instead of an "aralkyl". Appropriate correction is required.

Claim 4 is objected to because of the following informalities: a semi-colon is at the end instead of a period. See MPEP 608.01 (m). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claim 6 is particularly vague and indefinite given that the sentence contains the term "and" which indicates that additionally limitation is required in the claim and yet such limitation is missing (**in sentences 5 of claim 33 and sentence 4 of claim 34**). Given that applicant did not particularly point out what the additional limitation in the claim entails, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claim is unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the sake of compact prosecution, the Examiner will construe that the stated claim contains no further limitation.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 9 of copending Application No. 10/986485 (hereinafter Helton US Patent Application No. '485). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a

composition containing a compound of formula I further substituted by a formula III and a pharmaceutical carrier. The claimed invention and co-pending application Helton '485 are rendered obvious over another as the claimed invention teaches a method containing a composition comprising a subgenus of compounds with a alkyl group at the R6 position (i.e. the R6 of formula IIII) whereas Helton '485 teaches a subgenus of compounds containing a "hydrogen" at the same R6 position. Consequently, the Examiner contends that these compounds are obvious variants and therefore expected to behave similarly. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/986485.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent 6,770,638 B2 (hereinafter Fick US Patent Application No. '638). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a composition containing a compound of formula I further substituted by a formula III and a pharmaceutical carrier. The claimed invention and co-pending application Fick '638 are rendered obvious over another as the claimed invention teaches a subgenus of compounds with a alkyl group

at the R6 position (i.e. the R6 of formula IIII) whereas Fick '638 teaches a subgenus of compounds containing a "hydrogen" at the same R6 position. Consequently, the Examiner contends that these compounds are obvious variants of one another and therefore expected to behave similarly. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of U.S. Patent No. 6,770,638 B2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

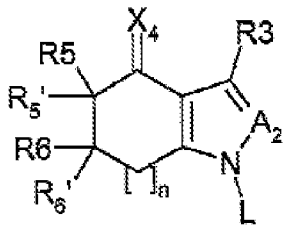
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fick et al. (WO 03/011396 A1, cited by applicant and filed on an IDS 1449).

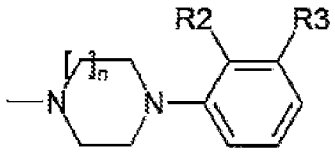
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

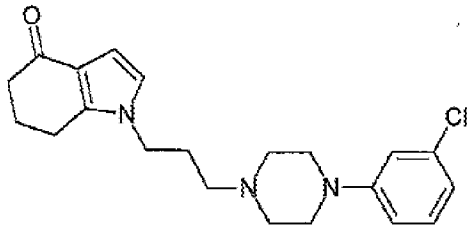
Fick et al. teach tetrahydroindolone and purine derivatives linked to arylpiperazines in pharmaceutical compositions containing a pharmaceutical excipient useful in treating anti-psychotic disorders (see abstract, pg. 1, paragraph 0002, and pg. 41, paragraphs 0129-0130). Fick et al. further teach that the compounds consists of two moieties, moiety A and B which a tetrahydroindolone comprises a moiety A linked through a linker L to a moiety B, where B is an arylpiperazinyl moiety (see abstract and pg. 2, paragraph 0005). Fick et al. teach that the A moiety is an e-10 atom bicyclic moiety in which five aromatic membered ring has 1 to 2 nitrogen atoms with the following formula I:



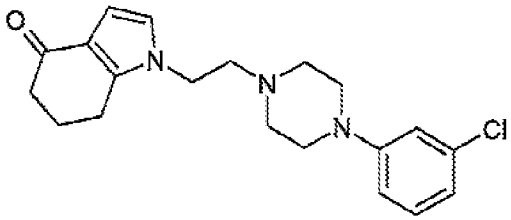
wherein formula I is bonded to a hydrocarbyl linker; A2 is C; R3 is hydrogen; X4 is O; R5 and R5' are hydrogen; R6 and R6' Are hydrogen; and n is 1 (see pgs. 4-5, paragraphs 0011-0013). The hydrocarbyl linker is preferably with the structure (CH2)m wherein m is an integer from 1 to 6 or wherein the preferred linker has m equal to 2, 3, or 4 (see pg. 12, paragraph 0045). As for the B moiety, it is an arylpiperazine or derivative having the structure of formula VII:



where R2 is H, alkyl, hydroxy, halo, alkoxy, cyano; R3 is H, alkyl, hydroxy, methoxy, halo, alkoxy, trifluoromethyl, nitro, amino, aminocarbonyl, aminosulfonyl; or where R2 and R3 can be taken together to form a 5 to 6 member aromatic or non-aromatic ring, which can contain 0 to 3 heteroatoms selected from the group of N, O, or S. and n=1 (see pg. 12, paragraphs 0047 and 0049). Particularly, Fick et al. teach various compounds such as Neo-363



and NEO-376



that render obvious applicant's invention (see pgs. 17-19, compounds 3 & 6).

Fick et al. do not specifically teach compounds wherein R6 is an alkyl group.

However, the Examiner contends that while Fick et al. do not teach R6 to be an alkyl group, Fick et al. do teach R6 to be a hydrogen atom. It is generally noted

that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 126 U.S.P.Q. 477, 53 U.S. P.Q. 40 (C.C.P.A. 1942); In re Druey, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C. P.A. 1963); In re Lohr, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); In re Hoehsema, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); In re Wood, 582 F.2d 638, 199 U.S. P.Q. 137 (C.C.P.A. 1978); In re Hoke, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.PA.A. 1977); Ex parte Fauque, 121 U.S.P.Q. 425 (P.O.B.A. 1954); Ex parte Henkel, 130 U.S.P.Q. 474, (P.O.B.A. 1960). Given that applicant did not provide unexpected or unobvious results of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to substitute the “H” group to a “methyl”. Moreover, the Examiner contends that such compounds are obvious variants of one another and are therefore expected to behave similarly given their similar structure.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute a methyl group at the R6 position for the hydrogen since both compounds are obvious variants and structurally similar and thus expected to behave similarly. Thus, given the teachings of Fick et al., one of ordinary skill would have been motivated to formulate the compounds of Fick et al. with a methyl group at the R6 position of formula VII with the reasonable expectation of providing compounds that are highly bioavailable and useful in the treatment of psychotic disorders.

Objections

Claims 7-8 and 19-20 are objected to because of the following informalities: Claims are dependent upon rejected claims. Appropriate correction is required.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

05/13/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617